



**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/308,237	05/21/99	OHKI	H 0018-1052-0P

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HM12/1209

EXAMINER

BORIN, M

ART UNIT	PAPER NUMBER
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1654

DATE MAILED:

12/09/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/308,237

Applicant(s)

Ohki et al.

Examiner

M. Borin

Group Art Unit

1654



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-14 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-14 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

X Sequence Listing Letter

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **Part III DETAILED ACTION**

Claims 1-14 are currently pending.

Please see the attached NOTICE TO COMPLY WITH SEQUENCE RULES which sets its own period for response.

Claim 12 is in "use" format. For the purposes of restriction requirement the claim is considered as "method of use" claim.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-9, 11, 13 drawn to cyclic polypeptides and their composition.
- II. Claim 10, drawn to method of making of peptides of Group I.
- III. Claims 12, 14, drawn to method of use of peptides of Group I.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is the technical feature that links Groups I-III. Group

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II is not the contribution over the prior art because it is suggested by references teaching cyclic polypeptides having core structure of claim 1. See, for example, references D1-D3 described in the International Preliminary Search Report, and the discussion of the lack of unity presented in the International Preliminary Search Report. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2.

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, e.g., derivatizing a linear peptide first and then cyclizing it.

Inventions I and III are related as product and method of making. In the instant case the method of use can be practiced with a broad variety of drugs beyond the claimed peptides. Further, the product as claimed can be used in a materially different processes such as peptide synthesis.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP 821.04)

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Upon election of any single one of the Groups from above the following election of species is hereby required:

**Species Requirement**

The claims of Groups I-III are individually or dependently directed to a plurality of disclosed patentably distinct species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. See, for example, references D1-D3 described in the International Preliminary Search Report, and the discussion of the lack of unity presented in the International Preliminary Search Report. The claims of the Groups are individually or dependently directed to a plurality of disclosed patentably distinct species of peptides having various R1 and R2 residues. Applicant is required under 35.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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Applicant is required, in response to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non - responsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang can be reached on (703) 308-0254. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



MICHAEL BORIN, PH.D.  
PATENT EXAMINER